THE RESTRICTION REQUIREMENT

The Examiner has required restriction to one of the following Groups:

I. Claims 1-45 drawn to a pharmaceutical composition comprising at least one insulin secretagogue and at least one FBPase inhibitor herein, classified in class 514, subclass 708, 709, 712, and 592 for example.

II. Claims 46-74 drawn to a method of treating a mammal having diabetes comprising administering at least one insulin secretagogue and at least one FBPase inhibitor herein, classified in class 514, subclass 708, 709, 712, and 592 for example.

III. Claim 75-98 drawn to a pharmaceutical composition comprising insulin or insulin analogue and at least one FBPase inhibitor herein, classified in class 514, subclass 708, 709, 712, and 592 for example.

IV. Claims 99-114 drawn to a method of treating a mammal having diabetes comprising administering insulin or insulin analogue and at least one FBPase inhibitor herein, classified in class 514, subclass 708, 709, 712, and 592 for example.

Applicants hereby provisionally elect the invention of Group I, with traverse. Applicants reserve their right to prosecute the non-elected subject matter in this application or in a divisional application. Applicants respectfully request reconsideration and withdrawal of the restriction requirement.

The Examiner contends that Groups I and II are related as product and process of use. The Examiner makes the same argument for Groups III and IV. The Examiner also believes that Groups I and III and Groups II and IV are not related to each other. The Examiner explains this position saying:

> Therefore, the criteria for distinct inventions: (1) the process for using the product as claimed can be practiced with another materially different product. In the instant case, for example, insulin secretagogue alone or one FBPase inhibitor herein alone (another materially different product from the instant claimed invention) may be used in a method of treating a mammal having diabetes.
>
> Inventions Group I and III; and Group II and IV are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. (citations omitted) In

> the instant case, Inventions Group I and III are drawn to two separate and distinct compositions, Therefore, they have different modes of operation. Inventions II and IV are drawn to two separate and distinct methods because of employing two separate and distinct compositions, Therefore, they have different modes of operation.
>
> Each above product and method of treatment relates to a separate and distinct area of pharmaceutical technology. The search for all inventions would place an undue burden on the Office in view of the diversity of the medical disorders to be treated and the corresponding diversity in the field of search for each. (Restriction Requirement p. 3)

According to MPEP § 803, two criteria are required for proper restriction: 1) that the inventions be independent or distinct; and 2) that there be a serious burden on the examiner. The Applicants believe that the Examiner has not met either criteria.

First, the Applicants believe that the inventions in Groups I, II, III, and IV are not independent or distinct. The Applicants believe that the two compositions (I and III) would have similar modes of action within the body resulting in similar effects on the body. Thus, the methods claimed (II and IV) do not meet the USPTO criteria of having "different modes of operation."

Furthermore, the Applicants believe that the inventions in Groups I and II (or III and IV) are not independent or distinct. Inventions I and II (III and IV) are not independent or distinct, because it has not been shown that the claimed methods can be used with materially different compounds. The Group II claims are related to the Group I claims as methods of treatment using the same drugs as in the composition claims (Group I). The same is true for Group IV (method) and Group III (composition).

Second, the Applicants believe that there would not be an undue burden on the Examiner to search both groups together. By the Examiner's own admission, claims in all Groups are drawn to FBPase inhibitors, classified in class 514, subclass 708, 709, 712, and 592. Therefore, the FBPase inhibitor is a common denominator to all Groups.

Since Group II(IV) is drawn to methods of using Group I(III), a search of Group I(III) will necessarily turn up prior art on Group II(IV). Because of this overlap, the Applicants respectfully

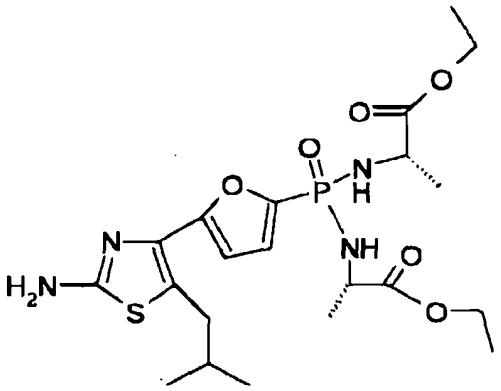
submit that the search of Groups I and II (or III and IV) together will not pose an undue burden on the Examiner.

Applicants respectfully submit that all four groups should be searched and examined together. But should the Examiner still believe some sort of restriction is proper, Applicants suggest that there should only be a two way restriction at most. Groups I and II are properly examined together. Likewise, Groups III and IV are also properly examined together.

THE ELECTION OF SPECIES REQUIREMENT

The Examiner further requires that the Applicants elect a single particular composition comprising specified compounds employed in Groups I-IV. The Applicants are further advised to include an identification of the species elected and a listing of all claims readable thereon.

The Applicants hereby elect the following species for initial examination with traverse. Applicants understand that if the Examiner allows a generic claim, that the election of species will be withdrawn. The FBPase inhibiting compound elected is the one with the following structure



The general class elected for insulin secretagogues is sulfonylurea antidiabetic agent. The specific compound is glyburide.

The claims from Group I reading thereon are 1-4, 11, 13, 22-23, 25-28, 30, 32-35, 37, 39-41. Should the Examiner conclude that Group II claims should be examined with Group I claims, the elected species read on the following Group II claims: 46-48, 50, 63-65, and 71-74.

The Examiner argues:

> Currently, Claims 1-114 are generic to a plurality of disclosed patentably distinct species (compounds) in pharmaceutical compositions and methods herein. The claims of Groups I-IV read on the employment of various compounds of with great diversity of chemical structure classified across class 514, the search for all of which presents an undue burden on the Office. It is noted that a reference to one combination of individual agents would not be a reference to another combination of individual agents under 35 U.S.C. 103.
>
> A "specie"[sic] is a specific compound and a specific disease or condition to be treated, with all parameters and/or substituent variable FULLY accounted for.

The Applicants respectfully contend that the claimed compositions of present sufficiently few species and that they can be readily evaluated together. Indeed a search of any of the species of the allegedly generic claims would, by necessity, include a search of art relevant to the other species of such claims. The Applicants submit that such a search would not be an undue burden on the Examiner.

For the foregoing reasons, the Applicants respectfully request the Withdrawal of the Restriction Requirement and Election of Species Requirement.

Respectfully Submitted,

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